

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

ABELEV, Gary
Dorsey & Whitney LLP
250 Park Avenue
New York, NY 10177
ETATS-UNIS D'AMERIQUE

Patent Mail Docketed
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| | | |
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| Date of mailing (day/month/year) 07 June 2007 (07.06.2007) | | |
| Applicant's or agent's file reference 185906/PCT | | IMPORTANT NOTICE |
| International application No. PCT/US2005/042408 | International filing date (day/month/year) 21 November 2005 (21.11.2005) | |
| Priority date (day/month/year) 24 November 2004 (24.11.2004) | | |
| Applicant THE GENERAL HOSPITAL CORPORATION et al | | |

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

DOCKETED

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Beate Giffo-Schmitt

Facsimile No. +41 22 338 82 70

e-mail: pt03.pct@wipo.int

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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|--|--|--|------------------|
| Applicant's or agent's file reference 185906/PCT | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/US2005/042408 | International filing date (<i>day/month/year</i>) 21 November 2005 (21.11.2005) | Priority date (<i>day/month/year</i>) 24 November 2004 (24.11.2004) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant THE GENERAL HOSPITAL CORPORATION | | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

| | |
|---|--|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Date of issuance of this report 30 May 2007 (30.05.2007) |
| | Authorized officer Beate Giffo-Schmitt e-mail: pt03.pct@wipo.int |

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To:

see form PCT/ISA/220

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/042408

International filing date (day/month/year)
21.11.2005

Priority date (day/month/year)
24.11.2004

International Patent Classification (IPC) or both national classification and IPC
INV. G01B9/02 A61B5/00

Applicant
THE GENERAL HOSPITAL CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Kunz, L

Telephone No. +49 89 2399-2628



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/042408

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/042408

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 2-16,19-57

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☒ the claims, or said claims Nos. 2-16,19-57 are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/042408

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-57 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-57 |
| Industrial applicability (IA) | Yes: Claims | |
| | No: Claims | 1-57 |

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

The following document (D) is referred to in this Written Opinion of the International Searching Authority:

D1 : WO 2004 / 057 266 A2

1. Objections under Article 6 PCT (Clarity)

- 1.1 The variations in wording between independent claims 1, 19, 32 and 37 as well as between the alternatives claimed in independent claims 1, 19 and 37 are such that the number of claims is not reasonable in consideration with the nature of the invention (Rule 6.1 (a) PCT). Furthermore, by giving seven different definitions for the same invention, the subject matter for which protection is sought is not clearly defined by the claims, contrary to the requirements of Article 6 PCT. Therefore, a statement concerning the requirements of Article 33 PCT is given only for the first claimed invention.
- 1.2 The claims are drafted in so vague terms and on such a level of abstraction that they are not clear in the light of the description and lack support by the description (Article 6 PCT).
The description concerns OCT interferometry for endoscopes (see pages 1 to 3, and figure 2). The goal of the invention is the provision of an interferometer where reference and sample arms traverse substantially the same path (see page 3, lines 31 to 33), in order to obviate problems associated with conventional fibre optic OCT probes (see page 3, lines 6 to 28). This goal is achieved by providing the beam splitter of the interferometer in the distal end of the endoscope, such that the "reference arm" becomes placed within the body of the catheter (see page 7, lines 5 to 16, and figures 3 and 4).
Independent claim 1, for example, is in its second embodiment drafted in so vague terms that its subject matter is anticipated by a bathroom including a mirror. Such a bathroom is namely an arrangement adapted to propagate at least one electro-magnetic radiation (light), comprising: a probe housing (the bathroom itself) and a section which is at least partially situated in the probe housing (area in front of the mirror) and configured to receive a first portion of the at least one electro-magnetic

radiation from a sample (e.g. person in front of the mirror) and a second portion of the at least one electro-magnetic radiation from a reference (mirror), wherein the first and second portions travel along substantially the same path (between the person and the mirror).

Such a level of abstraction of the claims is not appropriate and does not allow a positive statement as concerns the requirements of Article 33 PCT.

- 1.3 Claims 2 to 16 refer to the features of the second embodiment "defined" in independent claim 1. Therefore, these claims have to be excluded from the statement concerning the requirements of Article 33 PCT, which is given only for the first claimed invention.

2. Statement Concerning the Requirements of Article 33 PCT

- 2.1 Document D1 (see in particular page 10, line 1, to page 17, line 31, and figures 1, 2 and 5) describes an arrangement (36, 36a) adapted to propagate at least one electro-magnetic radiation (light from laser 43, 43a), comprising: a probe housing (36 in figure 1) and an interferometer (see figures 2 and 5) situated within the probe housing (36, 36a).

For these reasons, the subject matter of independent claim 1 is anticipated by document D1 and thus not new.

- 2.2 The features of claims 17 and 18 are also known from document D1 and thus do not add novel subject matter to the device defined in independent claim 1.
Claim 17: the interferometer shown in figures 2 and 5 is a Michelson interferometer;
Claim 18: the interferometer includes a section (l_1) configured to receive a first portion of the at least one electro-magnetic radiation from a sample (9) and a second portion of the at least one electro-magnetic radiation from a reference (surface 53, 53a), wherein the first and the second portions travel along substantially the same path (except for l_2).

- 2.3 The subject matter of the first claimed invention is also anticipated by DE-A-103 51 319, which is, however, a state of the art according to Rule 64.3 PCT.